PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	21 JUN 2010

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
22409-00501-	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US09/38932	31 March 2009 (31.03.2009)	31 March 2008 (31.03.2008)

Applicant

COCHLEAR AMERICAS

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US	Authorized officer
Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Linda Sholl
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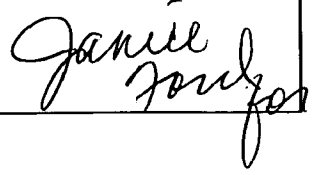

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 22409-00501-	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US09/38932	International filing date *(day/month/year)* 31 March 2009 (31.03.2009)	Priority date *(day/month/year)* 31 March 2008 (31.03.2008)
International Patent Classification (IPC) or national classification and IPC IPC(8): **A61F 2/18** (2009.01) USPC: 600/25		
Applicant COCHLEAR AMERICAS		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 29 January 2010 (29.01.2010)	Date of completion of this report 16 June 2010 (16.06.2010)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No.	Authorized officer Linda Sholl Telephone No 571-272-4391

Form PCT/IPEA/409 (cover sheet)(April 2007)

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3(a) and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-22 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 23-29 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1/11-11/11 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(c)).

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive Step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial Applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 4,5,8,9,11-14,20,21,24,25,27-30,34,35,37,38,40
The opinion as to Novelty was negative (No) with respect to claims 1-3,6,7,10,15-19,22,23,26,31-33,36,39
The opinion as to Inventive Step was positive (Yes)with respect to claims NONE
The opinion as to Inventive Step was negative(NO) with respect to claims 1-40
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-40
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-3, 6, 7, 10, 15-19, 22, 23, 26, 31-33, 36, and 39 lack novelty under PCT Article 33(2) as being anticipated by Leysieffer.

Referring to claim 1, Leysieffer, discloses a system for fitting a hearing prosthesis to a recipient, comprising: a stimulation arrangement configured to at least one of mechanically and acoustically stimulate the recipient's inner ear based on an input signal (Paras. [0042] and [0044]); a neural response detection arrangement configured to detect the recipient's neural responses to the stimulation (Paras. [0042] and [0044]); and a processor configured to assess the recipient's neural responses, and to adjust the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 2, Leysieffer, discloses the system of claim 1, wherein the input signal has a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]).

Referring to claim 3, Leysieffer, discloses the system of claim 1, wherein the stimulation arrangement comprises: an audio output device configured to generate an amplified audio signal representing the input signal (audiometer, Para. [0021]).

Referring to claim 6, Leysieffer discloses the system of claim 1, wherein the stimulation arrangement comprises: an actuator (transducer, Para. [0114]) configured to receive electrical signals representing the input signal and

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configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Para. [0114]).

Referring to claim 7, Leysieffer discloses the system 0 f claim 1, further comprising a signal generator to generate the input signal (audiometer, Para. [0021]).

Referring to claim 10, Leysieffer discloses the system of claim 1, wherein the processor is configured to implement, in real-time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042} and [0044]).

Referring to claims 15, Leysieffer discloses the system of claim 1, wherein the system is configured to be integrated into the hearing prosthesis (coupling rod 55, Fig. 10).

Referring to claim 16, Leysieffer discloses the system of claim 15, configured to periodically fit the hearing prosthesis (coupling rod 55) to the recipient during operation of the prosthesis (Para. [0111]; "and has a surface composition and surface size such that, by placing the coupling end against the coupling site, dynamic tension-compression force coupling of the coupling element and ossicular chain occur due to surface adhesion which is sufficient for secure mutual connection o| the coupling element and the ossicular chain.).

Referring to claim 17, Leysieffer discloses a hearing prosthesis, comprising: a stimulation arrangement configured to at least one of mechanically and acoustically stimulate the recipient's inner ear based on an input signal (Paras. [0042] and [0044]); a neural response detection arrangement configured to detect the recipient's neural responses to the stimulation (Paras. [0042] and [0044]); and a processor configured to assess the recipient's neural responses (Para. [0042]), and to adjust the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 18, Leysieffer discloses the prosthesis of claim 17, wherein the input signal has a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]).

Referring to claim 19, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an audio output device configured to generate an amplified audio signal representing the input signal (audiometer, Para. [0021]).

Referring to claim 22, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Para. [0114]).

Referring to claim 23, Leysieffer discloses the prosthesis of claim 17, further comprising a signal generator to generate the input signal (audiometer, Para. [0021]).

Referring to claim 26, Leysieffer discloses the prosthesis of claim 17, wherein the processor is configured to implement, in real time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042] and[0044]).

Referring to claim 31, Leysieffer discloses a method for fitting a hearing prosthesis to a recipient, comprising: at least one of mechanically and acoustically stimulating the recipient's inner ear (Para. [0044]); detecting the recipient's neural responses to the stimulation (Para. [0044]); assessing the recipient's neural responses (Para. [0042]); and adjusting the operation of the hearing prosthesis based on the assessment of the neural responses (Para. [0042]).

Referring to claim 32, Leysieffer discloses the method of claim 31, further comprising: generating a signal having a frequency spectrum comprising a broad range of audible frequencies (Para. [0109]); and stimulating the recipient's inner ear based on the generated signal (Para. [010g]).

Referring to claim 33, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: acoustically stimulating the recipient with an audio output device configured to generate an amplified audio

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signal representing an input signal (audiometer, Para. [0021]).

Referring to claim 36, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, wherein the actuator is coupled to the recipient's ossicular chain, and wherein the ossicular chain delivers the vibration to the recipient's inner ear (Pare. [0114]).

Referring to claim 39, Leysieffer discloses the method of claim 31, further comprising: implementing, in real time, a set of algorithms which assess the neural responses, and adjust the hearing prosthesis operations (Paras. [0042] and [0044]).

Claims 4, 5, 20, 21, 24, 25, 34, and 35 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Leysieffer et al.

Referring to claim 4, Leysieffer discloses the system of claim 1, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. However, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal, as taught by Leysieffer et al, to reduce acoustic feedback.

Referring to claim 5, Leysieffer discloses the system 0 f claim 1, wherein the stimulation arrangement comprises: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]); an elongate rod extending longitudinally from the actuator (transducer, Paras. [0114] and [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (Paras. [0012] and [0013], "its active transducer element is located itself in the middle ear region in the tympanic cavity"). However, Leysieffer does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surfaceis substantially orthogonal to a longitudinal axis extending through the actuator. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Referring to claim 20, Leysieffer discloses the system of claim 17, wherein the stimulation arrangement comprises: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals, and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration ol the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Pare. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular

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canal, as taught by Leysieffer et al, to reduce acoustic feedback.

Referring to claim 21, Leysieffer discloses the prosthesis of claim 17, wherein the stimulation arrangement comprises: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]); an elongate rod extending longitudinally from the actuator connecting the actuator (transducer, Paras. [0114] and [0036]) to the stapes prosthesis such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (Paras. [0012] and [0013], "its active transducer element is located itself in the middle ear region in the tympanic cavity"). However, Leysieffer does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig.5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Referring to claims 24 and 25, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach [Claim 24] the detection arrangement comprises: first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 25] the prosthesis of claim 24, further comprising: a sense amplifier configured to receive signals from the first and second contacts. Yet, Leysieffer et al., teaches a cochlear implant [Claim 24] wherein the detection arrangement (receiver/stimulator 22, Para. [0090]) comprises: first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 25] the system of claim 8, further comprising: a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]) configured to receive signals from the first and second contacts (stim 1 or stim 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and a sense amplifier configured to receive signals from the first and second contacts, as taught by Leysieffer et al., in order to prevent damage to the inner ear.

Referring to claim 34, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: directly mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals (transducer, Para. [0114]), and a coupler (coupling rod, [0036]) connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's semicircular canal (tympanic canal, Para. [0013]). However, Leysieffer does not teach a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal. Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having a first end configured to be positioned abutting an opening in a (oval window 22, Col. 9, Lns. 7-31, Fig. 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having a first end configured to be positioned abutting an opening in the semicircular canal, as taught by Leysieffer et al, to reduce acoustic feedback.

Referring to claim 35, Leysieffer discloses the method of claim 31, wherein stimulating the recipient comprises: directly mechanically stimulating the recipient's inner ear with a stimulation arrangement (Paras. [0042] and [0044]) comprising: an actuator (transducer, Paras. [0114] and [0036]) configured to receive electrical signals representing the input signal and configured to vibrate in response to the electrical signals; and an elongate rod (coupling rod, Para. [0036]) extending longitudinally from the actuator connecting the actuator to the stapes such that vibration of the actuator results in waves of fluid motion in a recipient's scala tympani (tympanic canal, Para. [0013]). However, Leysiefler does not teach a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator.

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Yet, Leysieffer et al. discloses a stapes prosthesis (stirrup prosthesis 28) having first and second ends (the bottom and right top ends of stirrup prosthesis 28, as shown in Fig. 5), the first end (the bottom end of stirrup 28, Fig. 5) having a surface configured to be positioned abutting the round window (oval window 22) in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator (Col. 9, Lns. 7-31, Fig.5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a stapes prosthesis having first and second ends, the first end having a surface configured to be positioned abutting the round window in the recipient's cochlea, and wherein the first end surface is substantially orthogonal to a longitudinal axis extending through the actuator, as taught by Leysieffer et al., in order to reduce acoustic feedback and provide adequate sound quality.

Claims 8, 9, 11, 27, 37, 38, and 40 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Ibrahim et al. (hereinafter referred to as Ibrahim).

Referring to claims 8 and 9, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach [Claim 8] wherein the detection arrangement comprises: first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 9] the system of claim 8, further comprising: a sense amplifier configured toreceive signals from the first and second contacts. Yet, Ibrahim teaches a cochlear implant [Claim 8] wherein the detection (receiver/stimulator 22, Para. [0090]) arrangement comprises: first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and [Claim 9] the system of claim 8, further comprising: a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]) configured to receive signals from the first and second contacts (stim 1 or stim 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a first and second electrical contacts disposed on the recipient's inner ear to detect the recipient's neural responses to the stimulation; and a sense amplifier configured to receive signals from the first and second contacts, as taught by Ibrahim, in order to prevent damage to the inner ear.

Referring to claim 11, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach the processor is configured to assess the neural responses by comparing the responses to target neural responses. Yet, Ibrahim teaches a cochlear implant wherein the processor (circuitry 10, Fig. 2) is configured to assess the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a processor is configured to assess the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Referring to claim 27, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach the processor is configured to assess the neural responses by comparing the responses to target neural responses. Yet, Ibrahim teaches a cochlear implant wherein the processor (circuitry 10, Fig. 2) is configured to assess the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a processor is configured to assess the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Referring to claims 37 and 38, Leysieffer discloses the method of claim 31. However, Leysieffer does not teach wherein [Claim 37] detecting the recipient's neural responses to the stimulation comprises: detecting the neural responses with first and second electrical contacts disposed on the recipient's inner ear; and [Claim 38] the method of claim 37, further comprising: delivering signals representing the detected neural responses to a sense amplifier. Yet, Ibrahim teaches a method [Claim 37] wherein detecting the recipient's neural responses to stimulation comprises: detecting neural responses using first and second electrical contacts (stim 1 or stim 2, Paras. [0090] and [0101]) disposed on the recipient's inner ear; and [Claim 38] the method ot claim 37, further comprising: delivering signals representing the detected neural responses to a sense amplifier (receiver/stimulator 22, Paras. [0090] and [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysiefler's system to include provide the arrangement above, as taught by Ibrahim, in order to detect and prevent damage to the inner ear.

Referring to claim 40, Leysieffer discloses the method of claim 31. However, Leysieffer does not teach

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assessing the neural responses comprises: comparing the detected responses to target neural responses. Yet, Ibrahim teaches assessing the neural responses by comparing the responses to target neural responses (Para. [0101]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include a assessing the neural responses by comparing the responses to target neural responses, as taught by Ibrahim, to automatically adjust the implant.

Claims 12-14, and 28-30 lack an inventive step under PCT Article 33(3) as being obvious over Leysieffer, in view of Bachler.

Referring to claims 12 - 14, Leysieffer discloses the system of claim 1. However, Leysieffer does not teach [Claim 12] the processor is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range; [Claim 13] the processor is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient; and [Claim 14] the processor is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing. Yet, Bachler teaches a loudness limiter that includes [Claim 12] a processor (processing unit 3) that is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range (Col. 3, Lns. 30-33); [Claim 13] the processor (processing unit 3) is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient (Col. 3, Lns. 30-33; The user will automatically adjust his speech according to what he hears.); and [Claim 14] the processor (processing unit 3) is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing (Col. 3, Lns. 35-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include the arrangement above, as taught by Bachler, to prevent damage to the user's ears.

Referring to claims 28-30, Leysieffer discloses the prosthesis of claim 17. However, Leysieffer does not teach [Claim 28] the processor is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range; [Claim 29] the processor is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient; and [Claim 30] wherein the processor is configured implement one or more safety guidelines which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's hearing. Yet, Bachler teaches a loudness limiter that includes [Claim 28] a processor (processing unit 3) that is configured to adjust the operation of the hearing prosthesis to provide at least one of equal loudness and optimal loudness restoration across a desired audible frequency range (Col. 3, Lns. 30-33); [Claim 29] the processor (processing unit 3) is configured to adjust the operation of the hearing prosthesis to improve speech perception by the recipient (Col. 3, Lns. 30-33; The user will automatically adjust his speech according to what he hears.); and [Claim 30] the processor (processing unit 3) is configured implement one or more safety guidelines Which prevent adjustment of the hearing prosthesis that would result in stimulation damaging to the recipient's headng (Col. 3, Lns. 35-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leysieffer's system to include the arrangement above, as taught by Bachler, to prevent damage to the user's ears.

Claims 1-40 meet the criieria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.